b.) Remarks

Claim 9 has been amended for better idiomatic usage only. Additionally, claim 8 has been amended to better recite a preferred embodiment of the present invention. Accordingly, no new matter has been added.

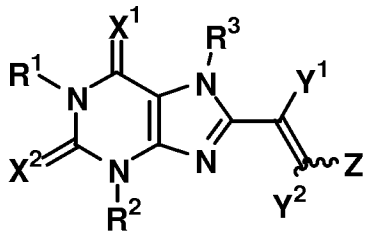
Claims 1, 6-8, 10 and 12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Shimada (*Bioorganic & Medicinal Chemistry Letters*, Vol. 7, No. 18 (1997) 2349-52) in view of Sako (U.S. Patent No. 6,562,375), both of record, and Harrison (U.S. Patent No. 5,573,776, newly cited), and claims 9 and 11 are rejected as being obvious over this art in view of Okuda (U.S. Patent No. 4,654,206).

Additionally, claims 1, 6-8, 10 and 12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Suzuki in view of Sako and Harrison, and claims 9 and 11 are rejected as being obvious over this art in view of Okuda.

Lastly, claims 1, 6-8, 10 and 12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hara (WO 01/32182) in view of Sako and Harrison, and claims 9 and 11 are rejected as being obvious over this art in view of Okuda.

This rejection is respectfully traversed. Prior to setting forth their bases for traversal, however, Applicants would briefly like to discuss the salient features of the present invention and inter alia its patentable nature over the prior art.

As the Examiner is well-aware, the present invention is a method for suppressing dimerization of a particular xanthine compound or salt represented by formula (IA)



(IA)

in a solid formulation. As recited in the pending claims, the process comprises providing in the solid formulation an iron oxide, so as to effectively suppress dimerization of the xanthine compound.

These features are not taught or suggested by the prior art, even taken together. That is to say, as discussed below, there is no prima facie obviousness.

Shimada teaches that 8-strylxanthines undergo rapid isomerization when exposed to light in dilute solution. First, isomerization is not the same as dimerization and second, isomerization occurs by a completely different mechanism than dimerization. Moreover, Shimada does not refer to any stability issue of 8-styrylxanthines in a solid formulation, let alone dimerization.

Sako teaches that changes in drug release from sustained-release preparations containing polyethylene oxide can be prevented by adding yellow ferric oxide or red ferric oxide. Sako teaches the photo-activity of polyethylene oxide. Sako teaches

> "As shown in Table 1, it was estimated that the drug release rate of the Comparative Example in which the preparation did not contain yellow ferric oxide and/or red ferric oxide would increase with exposure to light because the matrix erosion percentage increased." (Col. 7, lines 57-61).

Sako teaches that a number of bonds of polyethylene are cut by light, which is completely irrelevant to dimerization. However, Sako does not teach photo-activity of any drug, let alone Applicants'. The structures of polyethylene oxide are quite different from those of the xanthine compounds.

Harrison, of course, is relied only as showing a controlled release preparation comprising xanthine derivatives and polyethylene oxide. Harrison does not discuss any chemical stability issues of a xanthine compound, let alone the dimerization of such.

Similarly as all the foregoing references, Suzuki and Hara, too, do not teach that there is a stability issue with the xanthine compounds in coated solid formulation nor the xanthine compounds undergo dimerization.

In view of the above amendments and remarks, Applicants respectfully submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1 and 6-12 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Lawrence S. Perry/
Attorney for Applicants
Lawrence S. Perry
Reg. No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

LSP/ac

FCHS_WS 3592980_1.DOC